

REMARKS

Applicants thank Examiner Chernyshev for her time and comments during an interview conducted with the undersigned attorney on April 15, 2004. Applicants acknowledge and thank the Examiner for indicating that claims 1 and 2 as previously presented and claims 4-7 and 26-28 as submitted March 15, 2004 in the Amendment and Response to a Final Office Action (mailed January 13, 2004) are allowable. Applicants note that the Examiner did not acknowledge the status of claim 29 in the Interview Summary. Applicants respectfully submit that claim 29 is also allowable. The Examiner rejects claim 8, 23, and 24 as submitted in the Amendment and Response to the Final Action, asserting lack of enablement under 35 U.S.C. § 112, first paragraph.

Reconsideration of the present application in view of the above Amendments and following remarks is respectfully requested. At present, whether the Examiner intends to enter the after-final Amendment dated March 15, 2004 is unclear. Accordingly, Applicants submit in this Response claims 4 and 5 as amended in the Amendment and Response filed March 15, 2004, under 37 C.F.R. § 1.116. Claim 8 has been amended herein to more clearly point out and distinctly claim an embodiment of Applicants' invention and to place the claim in condition for allowance. New claims 26-29 are presented as submitted in the Response filed March 15, 2004, which are added to further increase the clarity of the claims and to expedite prosecution of this application. Claims 26-29 contain subject matter that had been recited in claims 5-8, respectively, prior to the amendments submitted on March 15, 2004. Applicants hereby cancel claims 23 and 24 without acquiescence to any rejection and without prejudice to further prosecution of this subject matter in a related divisional, continuation, or continuation-in-part application. Support for the amended claims may be found in the application as originally filed, for example, at page 3, lines 3-14. No new matter has been added.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT)

The Final Office Action rejects claim 4 and dependent claims 5-8 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Specifically, the Action asserts that undue experimentation would be required to determine how to make and use the claimed nucleic acid

that comprises (1) a polynucleotide sequence that is complementary to a sequence encoding a polypeptide and (2) a polynucleotide sequence encoding a heterologous polypeptide.

During a telephonic interview with the Examiner, the Examiner asserted that claim 8 as amended in the Response submitted after Final lacks enablement. Specifically, the Examiner asserted that undue experimentation would be required to make and use a method of producing a polypeptide using a nucleic acid comprising a sequence complementary to a sequence encoding a polypeptide of SEQ ID NO:2 or 13. The Examiner also asserted that claims 23 and 24 were not enabled by the specification, alleging that the claims reciting, in pertinent part, a composition comprising a pharmaceutically acceptable carrier, encompass a therapeutic use.

Applicants respectfully traverse these rejections and submit that as disclosed in the present specification and recited in the instant claims, Applicants fully enabled the claimed invention at the time the application was filed. Applicants respectfully submit that in view of the Amendments submitted herewith, which include cancellation of claims 23 and 24 without prejudice or acquiescence, the rejection of these claims is rendered moot.

Applicants submit that by using methods taught in the specification and known in the art, a person skilled in the art is enabled by the instant application to make and use, readily and without undue experimentation, a method of producing a polypeptide that comprises an amino acid sequence set forth in SEQ ID NO:2 or 13. As described in the specification and recited in the claims, the method comprises culturing a host cell in an appropriate culture medium to produce the polypeptide, wherein the host cell is transfected or transformed with an expression vector that comprises a nucleic acid molecule that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2 or 13 (*see, e.g.*, page 3, lines 7-14; page 40, line 26 through page 46, line 15).

Applicants further submit that the specification enables a person skilled in the art to make and use, readily and without undue experimentation, an isolated nucleic acid molecule comprising (a) a nucleotide sequence that encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 or 13 and (b) a nucleotide sequence encoding a heterologous polypeptide (*see, e.g.*, page 2, lines 16-27; page 3, lines 4-6; page 31, line 17 through page 32,

line 7). The instant disclosure further enables a skilled artisan to make and use an expression vector that comprises such a nucleic acid molecule, a host cell comprising such a vector, and a method for producing a polypeptide (*i.e.*, a fusion protein) comprising an ABCG4 transporter polypeptide having the amino acid sequence set forth in SEQ ID NO: 2 or 13 and a heterologous polypeptide (*see, e.g.*, page 3, lines 3-6; page 31, line 17 through page 33, line 13; page 40, line 26 through page 46, line 15).

Accordingly, Applicants respectfully submit that the requirements for enablement under 35 U.S.C. § 112, first paragraph, are met and request that this rejection of the claims be withdrawn.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Final Office Action rejects claims 8 and 23-24 under 35 U.S.C. § 112, second paragraph, for indefiniteness. In particular, the Action asserts that claim 8 is vague and indefinite with respect to which polypeptide is produced by the claimed method and that the nucleic acid of claim 4, upon which claim 8 depends, does not encode a polypeptide (see summary of enablement rejection above). The Action asserts that claim 24 recites SEQ ID NOS: 1, 3, and 12 as “antisense nucleic acid molecules” while the Sequence Listing states that the sequences are not complementary sequences. The Action further alleges that claims 23 and 24 are vague and ambiguous with respect to recitation of the term “suitable carrier” without stating an objective for which the carrier is suitable.

Applicants respectfully traverse these grounds for rejection and submit that the instant claims particularly point out and distinctly claim what Applicants regard as their invention. Applicants submit that in view of the Amendments submitted herewith, which include cancellation of claims 23 and 24 without acquiescence to the underlying rejection, the rejection of these claims is rendered moot.

Applicants submit that in view of the submitted amendments that include amendments to claim 8 and the addition of new claim 29, the claims more clearly point out several embodiments of Applicants’ invention. In one embodiment, the invention is related to a method for producing a polypeptide comprising the amino acid sequence set forth in SEQ ID

NO:2 or 13, wherein the method comprises in pertinent part culturing a host cell that is transfected or transformed with an expression vector comprising a nucleic acid molecule that encodes a polypeptide having a sequence of SEQ ID NO:2 or 13. Furthermore, Applicants submit that the claims more clearly point out that the invention is directed in another embodiment to a method for producing the polypeptide encoded by nucleic acid molecule comprising (a) a nucleotide sequence that encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 or 13 and (b) a nucleotide sequence encoding a heterologous polypeptide. *See, e.g.*, specification at page 3, lines 7-14; 21-25; page 40, line 26 through page 41, line 18.

Accordingly, Applicants submit that the claims are definite and thus meet the requirements of 35 U.S.C. § 112, second paragraph. Applicants therefore request that the rejection of these claims be withdrawn.

Applicants respectfully submit that all remaining claims in the application are believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned at 206-622-4900.

Respectfully submitted,

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